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**SANS 1384:2006**

Edition 2

# **SOUTH AFRICAN NATIONAL STANDARD**

## **Plastics containers for parenteral solutions**

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1 dr lategan road groenkloof ☒ private bag x191 pretoria 0001  
tel: 012 428 7911 fax: 012 344 1568 international code + 27 12  
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**Table of changes**

<b>Change No.</b>	<b>Date</b>	<b>Scope</b>

**Foreword**

This South African standard was approved by National Committee StanSA SC 5140.36C, *Intravenous solutions, injectables and infusion sets – Plastics containers for parenteral solutions*, in accordance with procedures of Standards South Africa, in compliance with annex 3 of the WTO/TBT agreement.

This edition cancels and replaces the first edition (SABS 1384:1984).

Annexes A and B are for information only.

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## **Plastics containers for parenteral solutions**

### **1 Scope**

This standard covers requirements for plastics containers such as film bags or blow-moulded plastic bottles, having a total nominal capacity in the range 25 mL to 5 000 mL, for direct administration of aqueous infusion (injection) solutions. It does not cover containers for blood or blood products.

### **2 Normative references**

The following referenced documents are indispensable for the application of this document. All normative documents are subject to revision and, since any reference to a normative document is deemed to be a reference to the latest edition of that document, parties to agreements based on this document are encouraged to take steps to ensure the use of the most recent editions of the normative documents indicated below. Information on currently valid national and international standards can be obtained from Standards South Africa.

#### **2.1 Standards**

ISO 15747, *Plastics containers for intravenous injection*.

#### **2.2 Other publications**

*European Pharmacopoeia (EP)*.

*United States Pharmacopoeia (USP)*.

### **3 Definitions**

For the purposes of this document, the following definitions apply.

#### **3.1**

##### **acceptable**

acceptable to the authority administering this standard, or to the parties concluding the purchase contract, as relevant

#### **3.2**

##### **access port**

area of the infusion container consisting of the insertion point and the injection point, if applicable [ISO 15747]